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Original Research

Factors Associated with High Lethality in Newborns with Gastroschisis in a Reference Hospital Unit in Angola

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Abstract: Gastroschisis has an important impact on newborn (NB) mortality. In sub-Saharan Africa, the mortality rate remains high at around 60 per cent. This study analyzed the factors associated with lethality in newborns with gastroschisis in a reference hospital unit in Angola. An observational, descriptive, and cross-sectional, hospital-based study was carried out and included information from 361 clinical files of newborns with gastroschisis evaluated at the David Bernardino Paediatric Hospital from 1st January 2010 to 15th July 2021. The mean maternal age was 22.34±4.5 years (range:14-40 years); the mean birth weight was 2453.9±515.6 with a significant difference between discharged and deaths groups (p<0.001). The high lethality rate (96,1%) was associated with low birth weight (Exp β = 7.956; 95% CI 1.758 – 36.163; p =0.007), parity (Exp β = 0.296; 95% CI 0.096 – 0.919; p =0.035), as well as sepsis (Exp β = 4.827; 95%CI 1.119 – 20.814; p =0.035). The results show that the high lethality of gastroschisis is particularly associated with factors related to the NB such as birth weight, sepsis and parity.

Keywords: Newborn; Gastroschisis; Lethality; Angola.

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1. Introduction

In the last 60 years, gastroschisis has gone from a deadly disease condition to high survival rates, thanks to advances in modern neonatology and newborn surgery, with reported mortality rates of 4 to 7 % [1, 2]. On the other hand, mortality rates from gastroschisis in sub-Saharan Africa remained high at around 60 % [1-3]. Gastroschisis has an important impact on newborn mortality [1-5]. The incidence is around 2-5 per 10,000 births and its prevalence has increased by 30% in the last decade [1, 2, 5, 6]. The high survival rate registered in developed countries reflects the high cost of the available technological resources [1, 3, 4]. This is not the case in developing countries where a large part of the population lives below the poverty line and has limited access to basic public services, low income, high birth and neonatal mortality rates, poor health systems and marked cultural aspects [1, 3, 7].

These problems are associated with a lack of neonatal intensive care beds and a shortage of tertiary centers qualified to treat gastroschisis [2, 3, 8, 9]. Mortality from gastroschisis is higher in some low- and middle-income countries (100% in Uganda and Ivory Coast, 75% in Nigeria and 60% in Malawi and 29% in South Africa) and low in high-income countries with results of 0% reported in the United Kingdom [1, 10].

The need for early diagnosis and immediate surgical intervention constitutes essential factor of good prognosis [3, 5, 9-14]. Prenatal diagnosis can be made by measuring the alpha-fetoprotein produced by the gastrointestinal tract and fetal liver, as well as fetal ultrasound, which is considered the best way to stablish the diagnosis [3,9]. Prenatal monitoring is of great importance, as early termination of pregnancy can occur due to altered fetal vitality [2, 3, 15]. Due to the great advances and dissemination of ultrasound in pregnancy work-up over the last two decades, the diagnosis of congenital malformations has become possible even in the prenatal period [3, 5, 15, 16].

This possibility arouses the interest of obstetricians who, together with other professionals (fetal medicine specialists, pediatric surgeons, neonatologists), can intervene in the natural history of gastroschisis to guarantee a better before birth prognosis [11, 16-19]. Assessing the clinical and epidemiological health profile is an important and indispensable tool for planning and managing health services [17]. Infant mortality is an important indicator of a country's health and is also a marker of the human development index because it expresses not only biological causes, but mainly socioeconomic and environmental determinants of the population [3, 18, 20, 21].

In developed countries, mortality rates from gastroschisis range from 3 to 10%. However, it is the high morbidity that arouses interest of obstetricians who, together with other professionals (fetal medicine specialists, pediatric surgeons, neonatologists), can intervene in the natural history of gastroschisis in order to guarantee a better before birth prognosis period is associated with factors related to slow intestinal adaptation after surgery, the use of prolonged parenteral nutrition, prolonged central venous catheters, infections and kidney damage may influence the prognosis [1-3, 10]. The complexity of this malformation depends on its association with intestinal atresia, perforation, necrosis, and volvulus, intestinal malrotation, which necessary surgical management turns the condition into short bowel syndrome, resulting in prolonged hospital stay, which promotes an increase in comorbidity [3, 7, 9, 21-23].

Several studies have highlighted that gastroschisis is associated with factors such as maternal age below 20 years, low level of education, parity, consumption of licit, illicit and pharmacological substances, low birth weight and prematurity. However, there is a scarcity of studies on factors associated with high lethality rate due to gastroschisis in African populations, especially in sub-Saharan Africa. Although there are data in certain African populations, local studies are needed according to the pre- and postnatal conditions in newborns with gastroschisis [2, 3]. There are no data available in the medical literature on gastroschisis in Angola.

The aim of this study was to analyze the clinical and epidemiological profile and determine the association between potential maternal and newborn factors and the high lethality rate in a national reference hospital unit in Angola.

2. Method

2.1 Type and location of study

Observational descriptive study carried out from the clinical files of newborns diagnosed with gastroschisis and treated at the emergency David Bernardino Paediatric Hospital located in Luanda/Angola with a hospital-based sample of cases identified according to the diagnosis in 361 clinical files of newborns with gastroschisis evaluated at the David Bernardino Paediatric Hospital between 1st January 2010 and 15th July 2021. The information, firstly, was extracted from the records in the statistics books of the anaesthesiology, intensive care, and neonatology departments to find the potential clinical files based on the diagnosis of gastroschisis during the period of study. Clinical files were then searched based on the patient's name and medical diagnosis of gastroschisis in the wards' archives of the neonatology and intensive care departments, statistics department, and hospital's general archives.

Newborns diagnosed with gastroschisis who died in the emergency department before the surgical intervention were excluded. These are 2 newborns born by vaginal delivery at home accompanied by family members who were unaware of the newborns' clinical history information; they entered the emergency service dead.

2.2 Statistical analysis

Demographic characteristics of mothers and newborns with gastroschisis who died were compared with those who were discharged from the hospital. Continuous variables were presented as mean ± standard deviation and compared using the Student t-test for independent samples (e.g. maternal age, estimated gestational age and birth weight, etc.).

Categorical variables (e.g. in-hospital and out-of-hospital births, primiparas and multiparas) were analyzed using the chi-squared test. After bivariate analysis, multivariate logistic regression was used to calculate the adjusted odds ratio for death, comparing newborns who died with those who were discharged from hospital. Variables with a $p < 0.1$ in of being associated with an increased risk of mortality in the univariable analysis were included in the logistic regression analysis to find the determinants of the high mortality rate. Given the nature of the variables under study, the most appropriate regression model is the logistic regression model. To predict the occurrence of death (dependent variable) based on the variables Sepsis, Number of Births and Birth Weight, the analysis of the model proposed for this purpose was prepared.

The classification table, provided by SPSS, for a cut-off value of 0.5 (borderline probability) shows that the application of the logistic regression model: the observations verified as correct as the occurrence of death (1 – Yes) are 96.1%. The relationship between the hemoglobin value and the risk of dying was also assessed. Statistical significance was set at $p<0.05$. All statistical analyses were carried out using the "Statistical Package for the Socials Sciences (SPSS)" version 26.0 to Windows. (Illinois, USA).

3. Results

Regarding gestational age, 336 (93.1%) newborns were full-term, mean gestational age of 38.2±2.2 weeks, with no statistically significant difference between the death and hospital discharged groups. However, 326 (90.3%) of the newborns had simple gastroschisis. There was a statistically significant difference between the groups ($p <0.005$) regarding the birth weight and hemoglobin, with higher means in the newborns who were discharged from the hospital. The body temperature of the newborns admitted to the emergency room ranged from 32.1ºc to 39.8ºc, with a mean of 36.2 ± 1.08ºc, the heart rate (HR) was between 84 and 180 beats per minute (mean 133.0 ± 13.7 bpm), respiratory rate ranged from 12 to 140 cycles per minute (mean 52.0 ± 11.9 c/min), with no significant difference between the groups. Most of the delivery, 201 (55.7%) were out-of-hospital and 160 (44.3%) in-hospital.

Of all the newborns who were discharged, 8 (57.1%) cases were in-hospital deliveries, although 152 (43.8%) in-hospital deliveries ended in death. Less than half (40.2%) of the children had sepsis, but the mortality was as high as 97.9%. The mean waiting time from birth to the surgical procedure was 2.91 ± 0.85 hours, that was higher in newborns who died, although not statistically significant (2.92 ± 0.85 vs 2.50 ± 0.85 hours $p = 0.942$) (Table 1). It was also registered an association between low hemoglobin levels and the risk of death ($\chi2 = 5.797$; $p =0.05$).

Table 1. Status-Demographic and Physiological Parameters of the Mother and Newborn.

Parameters	Death (347)	Improved discharge (14)	Total (361)	*p*-value
Mother's age (years)	22,3± 4,57	22,9 ± 5,0	22,3± 4,5	0,498
Gestational age (week)	38,2 ± 2,17	38,0 ± 2,18	38,2± 2,2	0,948
Weight R/N (g)	2432,8 ±501,3	2976,43±606,71	2453,9± 515,6	< 0,001

Body temp R/N (ºC)	36,2±1,08	36,1±1,4	36,2±1,08	0,467
Heart rate (bpm)	133,0 ±13,0	141,±13,7	133,±13,7	0,159
Respiratory rate (c/min)	52 ± 12,0	52,0 ± 9,5	52,0±11,9	0, 451
Haemoglobin (g)	15,8 ± 3,3	17,2 ±3,6	15,8±3,3	0, 005
Glycaemia (mg/dL)	87,09±42,4	71,7±26,7	86,50±41,9	0, 739
Time spent in the emergency room (minutes)	545,8 ± 680,5	513,7± 110,3	553,4±99,3	0,034
Length of hospital stay	2,92 ± 0,85	2,50 ± 0,85	2,91±0,85	0,942
Hospitalisation time (min)	127,9 ± 115,01	391,57±163,35	138,13 ±127,57	<0,001
In-hospital delivery	152(43,8%)	8(57,1%)	160(44,3%)	0,386
Out-of-hospital delivery	195(56,2%)	6 (42,9%)	201(55,7%)	<0,001
Primiparous	117(33,7%)	8(57,1%)	125(34,6%)	0,003
Multiparous	230(66,3%)	6(42,9%)	236(65,4%)	0,016
Cyanosis	67(19,3%)	1(7,1%)	68(18,9%)	0,254
Skin pallor	86(24,8%)	1(7,1%)	87(24,01%)	<0,001
Parenteral nutrition	8(2,3%)	2(14,3%)	10(2,8%)	0,007

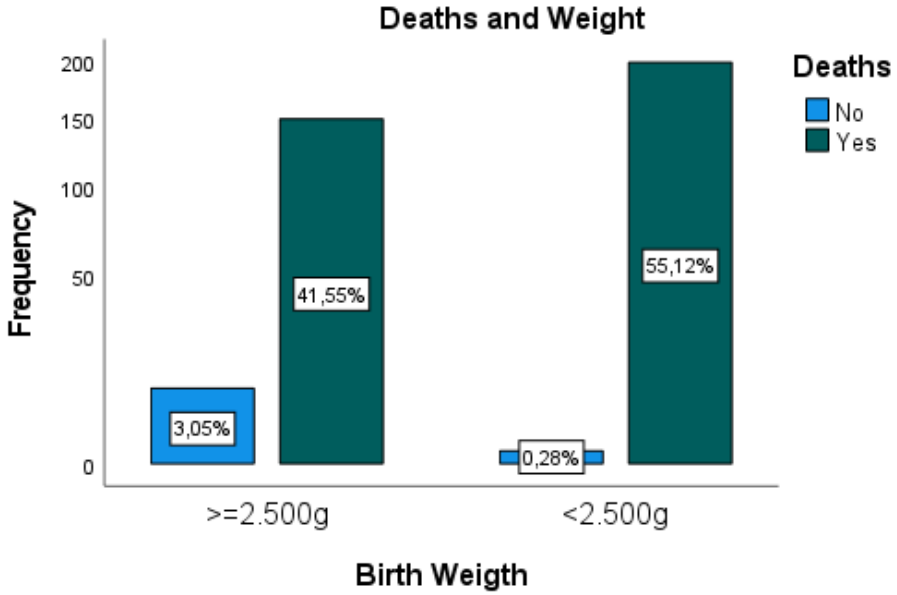
Multivariate logistic regression using the forward stepwise method showed that low birth weight is one of the main factors associated with an increased risk of death (Exp β = 7.956; 95%CI 1.758 - 36.163; p =0.007), followed by the number of births of the mother who appears in the second model (Exp β = 0.296; 95%CI 0.096 - 0.919; p =0.035), as well as sepsis (Exp β = 4.827; 95%CI 1.119 - 20.814; p =0.035), having become an aggravating factor in cases of low birth weight children. In the multivariable analysis (Table 2), birth weight, number of births, and sepsis were the main determinants of lethality in newborns with gastroschisis. Inferential statistical analysis allows us to conclude that the number of obtained results is associated with Birth Weight $\left(\chi^2_{(1)} = 11{,}130; p < 0{,}01; N = 361\right)$ (Figure 1).

Table 2. Determinants of Mortality in Newborns with Gastroschisis through Multivariate Logistic Regression.

Parameters					
	β±EPM	Wald	Exp (β)	IC 95%	p-value
Model 1					
Constant	-4,595 ± 0,711	41,808	0,010		< 0,0001
Birth Weight	2,076 ± 0,771	7,243	7,973	1,758 -36,163	0,007
Model 2					
Constant	-2,745 ± 1,067	6,616	0,064		0,010
Birth Weight	2,052 ± 0,774	7,022	7,781	1,689 -35,485	0,008
Number of Births	1,216 ± 0,577	4,439	0,296	0,096-0,919	0,035
Model 3					
Constant	-2,727 ± 1,076	6,426	0,065		0,011
Birth Weight	2,074 ± 0,779	7,089	7,956	1,728 -36,621	0,008
Number of Births	1,383 ± 0,600	5,310	0,251	0,077 - 0,813	0,021

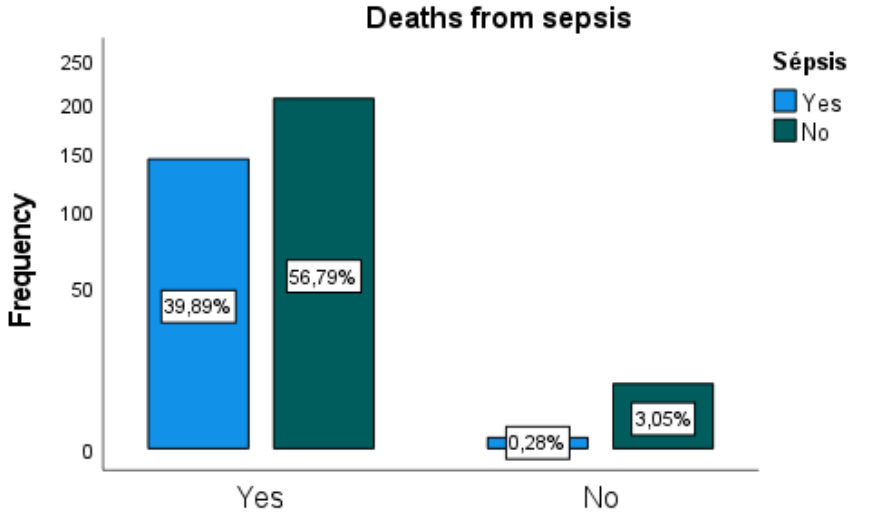
Sepsis	1,574 ± 0,746	4,458	4,827	1,119 -20,814	0,035

Figure 1. Inferential statistical analysis between Deaths and Birth Weight.



The Frequency distribution of the number of infections occurring in the presence of Sepsis. Given the inferential statistical analysis, it is possible to conclude that the number of infections occurring is associated with Sepsis (χ((1))^2=5,234 ;p=0,022;N=361). The *odds ratio*, that is, the possibility of it occurring when sepsis is diagnosed, is 7.73 times higher than in undiagnosed cases (Figure 2).

Figure 2. Frequency distribution of the number of infections occurring in the presence of Sepsis.



The percentage variation in the odds ratio for death (1), compared to the Number of Births ("1 – Primipara") decreases by 72.6% (-72.6%=100%×[0.274-1]), in the same sequence, in relation to the variable Birth Weight ("1 - ≥2500g) the percentage variation decreases by 91% (-91.0%=100%×[0.09-1]). It is worth highlighting that, when Sepsis is diagnosed ("1- yes") the chances of death are 8.796 (Exp(B)=8.796) times higher, indicating high mortality (Table 3).

Table 3. Association of sepsis, number of deliveries and birth weight with the occurrence of deaths of newborns with gastroschisis.

Variable	B	S.E	Wald	df	Sig	Exp(B)	95% C.I para EXP (B)	
							Less	Upper
Sepsis	2,174	1,060	4,205	1	,040	8,796	1,101	70,286
Number of birth	-1,296	,642	4,077	1	,043	,274	,078	,963
Birth Weight	2,745	1,057	6,751	1	,009	15,566	1,963	123,450
Constant	,019	1,271	0,00	1	,988	1,019		

a. Variable(s) inserted 1: sepsis, Number of births, Birth Weight.

According to the output, the model can be written as:

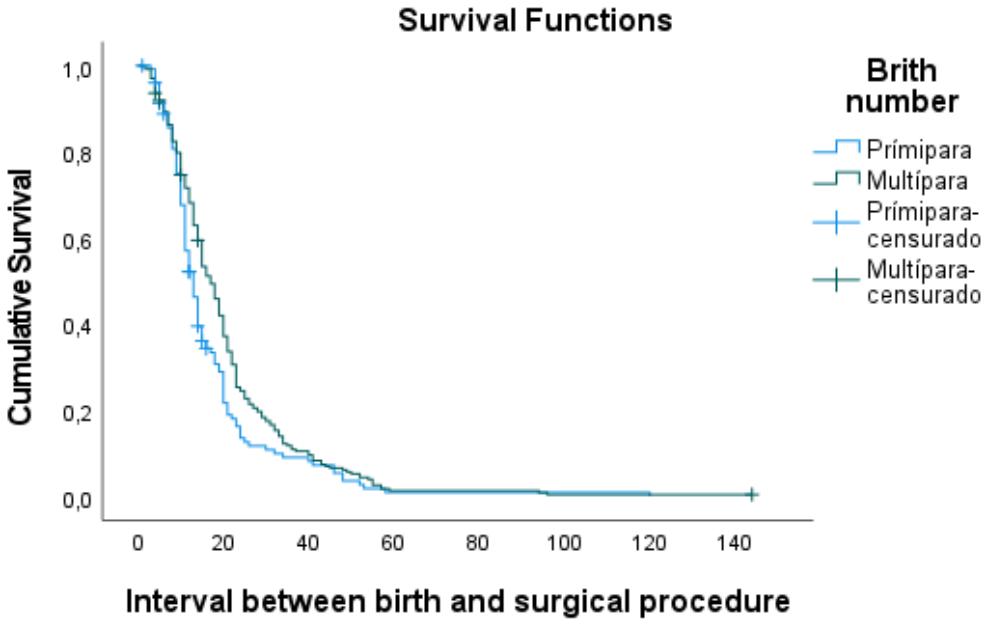
$$Logit(\hat{P}) = 0{,}019 + 2{,}174Sepsis(1) - 1{,}296\ Number\ of\ Births(1) + 2{,}745\ \text{Birth Weight}(1)$$

Or the model to estimate the probability $(\hat{P}_j)$ of each of the j (j=1,…,361) subjects belonging to the occurrence of death(1).

$$\hat{P}_j = \frac{e^{0{,}019+2{,}175\ Sepsis(1)-1{,}296\ Number\ of\ Births(1)+2{,}745\ Birth\ Weight(1)}}{1 + e^{0{,}019+2{,}174\ Sepsis\ (1)-1{,}296 Number\ of\ Births(1)+2{,}745\ Birth\ Weight\ (1)}}$$

The survival analysis will be compared in terms of their survival curves. The null hypothesis is that "there is no difference between the groups' survival curves". The table 3 generated from the SPSS software will be used to test the hypothesis. The testes of Low Rank $(\chi^2_{(1)} = 6{,}283, p = 0{,}012)$, Generalized Wilcoxon $(\chi^2_{(1)} = 8{,}204\ , p = 0{,}04)$ and Tarone – Ware $(\chi^2_{(1)} = 8{,}291\ , p = 0{,}04)$, all of them were statistically significant (Figure 3).

Figure 3. Survival curves.



4. Discussion

The reference on the current estimate of the Angolan population in 2024 of 34 million, predominantly young people, with a median age of 16.5 years, female dominance (51.3%)

and population growth of around 3.3% per year [8]. Of the 361 newborns studied, maternal age ranged from 14 to 40 years, the average was 22.3 ± 4.5 years, and 101 (27.98%) mothers were under 20 years old. Infant mortality is an important indicator of health and the human development index (HDI) in all countries [4, 21]. The prognosis for gastroschisis in low- and middle-income countries such as Angola is still quite bleak [3,5,24]. 361 newborn children (NB) with gastroschisis admitted to the David Bernardino Pediatric Hospital in Luanda over 12 years (2010 to 2021) were studied, with an overall lethality rate of 96.1%.

Gastroschisis-related mortality was associated with perinatal risk factors, such as low birth weight, sepsis, and a high number of deliveries, as well as low hemoglobin level, occurring mainly in the first week of life [1, 3, 5, 8, 9]. There was also a trend of high mortality for children who were born outside of a healthcare environment, as well as the delay in reaching the hospital to access specialized care. The country is made up of 18 provinces and the only referral hospital is in the capital; there are towns that are more than 2000 kilometers away.

The lack of prenatal diagnosis of gastroschisis in this study contrasts with what is reported in high-income countries, where more than 78-83% of patients with gastroschisis are diagnosed by ultrasound during the prenatal care [25]. In our reality, obstetric ultrasound is not routinely offered to all pregnant women. The country's care protocol for pregnant women only reserves the prenatal ultrasound for high-risk pregnancies. The lack of prenatal diagnosis of this congenital anomaly may have contributed to the high lethality rate reported in this study, due to the delay in referring these patients to a specialized unit that has the resources and experience to treat them.

The high frequency of deaths from gastroschisis is like other studies carried out in sub-Saharan African countries (>75%) [3]. Studies carried out in low- and middle-income countries such as Egypt, Zimbabwe and Uganda, the frequency of death was 62%, 84% and 98% respectively [2, 26, 27], findings close to those reported in this study, but different from Brazil where they recorded a survival rate of 87.1% [16], as well as in high-income countries, which report a survival rate of over 90% [25]. Another population-based study carried out in California with gastroschisis cases found that only 4.6% died [28].

Although our results point to low birth weight, parity and sepsis as the main factors associated with gastroschisis mortality, in low- and middle-income countries it is often associated especially with conditions linked to new born care, in particular the lack of prenatal diagnosis, home births or births in non-specialized centers, late surgery, lack of parenteral nutrition, lack of a silo, as well as a suitable Intensive Care Unit (ICU) for premature, low birth weight and newborns with malformations [3,13,16,29]. However, in high-income countries, the factors associated with gastroschisis mortality are inherent to the NB, such as prematurity, low birth weight, perforations, necrosis, and intestinal atresia [25,28-30].

Regarding the main causes associated with death, low birth weight was identified as the main cause in our study, which may be related to intrauterine growth delay or deficit, the existence of malformations, illnesses during pregnancy and the low socioeconomic status of families. NBs with gastroschisis and a birth weight of less than 2,500g in our study had a higher risk of death ($\chi 2 = 9.965$; $p = 0.002$). In the African context, low birth weight is a poor prognostic factor regarding the NB survival, especially in the first few weeks of life [2, 3, 26, 27]. Although no significant difference was identified between the two groups, sepsis was a risk factor associated with mortality in this cohort with OR = 2.540; 95%CI: 0.696 - 9.267 and was one of the main causes of death. Sepsis is a common cause of mortality in studies carried out in low- and middle-income countries [31, 32].

The increased risk of sepsis is due to the immaturity of the immune system, intestinal exposure, and central catheters, as well as prolonged starvation. In addition, these NBs often depend on intensive care and ventilatory assistance for several reasons, both of which are extremely limited in our institution. Improving the prenatal care and expanding ICU facilities can positively influence the prognosis in patients with gastroschisis. In this

study, the low hemoglobin level was also associated with a high frequency of deaths. Some factors may have influenced these values, such as the low availability of nutrients in the tissues and before birth sepsis, which was also associated with the occurrence of deaths. A study of NBs with gastroschisis carried out in Brazil showed that hemoderivatives were used more frequently in patients who died, a fact attributed to the coagulation disorders caused by sepsis [1]. Sugita et al. [30], in a study carried out in five pediatric surgical centers in Japan, showed that NBs with gastroschisis had lower hemoglobin values than those with omphalocele [30].

The high number of deliveries was associated with the occurrence of deaths. This may be linked to maternal age, which has been identified as one of the poor prognostic factors for the occurrence of gastroschisis [1, 3, 5, 8-10, 12-17, 21, 22]. Therefore, the mothers of the newborns studied were predominantly young, with ages ranging from 14 to 40 years and a mean of 22.3 ± 4.5 years. 101 (27.98%) mothers were under 20 years of age and more than half of them were multiparous with more than three children, what may suggest that there is a relationship between early motherhood, multiparity and the high mortality rate from gastroschisis. A study carried out at one of South Africa's most prestigious universities using data obtained from hospitals in Harare/Zimbabwe revealed that children born to mothers with ≥5 births were more likely to die, and the condition worsened in the presence of a congenital malformation, particularly gastroschisis [33, 34].

This article has important limitations, because it was carried out in a single public hospital that receives newborns diagnosed with gastroschisis from all over the country. This hospital does not have a computerized clinical data system; the clinical records were prepared and filed on sheets of paper, which is why the extraction of clinical data did not meet standardized criteria; it is a retrospective study with a convenience sample; bias due to the fact that data collection was performed on clinical records without any standardized computerized criteria, and some vital information was missing, such as the APGAR at the first and fifth minutes. Therefore, this study has strengths: 1) it is one of the first robust hospital-based studies carried out in Angola; 2) it represents the largest study to date establishing factors associated with lethality due to gastroschisis for a hospital population in Angola.

Implement measures to improve health indicators in newborns, especially in the prenatal period, and establish health policies to lower the neonatal mortality rate in middle/low-income countries.

5. Conclusion

The factors associated with lethality in newborns with gastroschisis are particularly related to the NB, such as low birth weight, parity, and sepsis, but no association was found with maternal and status-demographic factors. There is a need to improve basic neonatal care, early surgical management including preformed silos and bedside closure, provide parenteral nutrition and reducing time to access surgery can improve survival. This study provides support for a strong intervention in the care of newborns with gastroschisis, centralizing their birth in tertiary units and improving diagnosis during the prenatal follow-up with ultrasound scans to rule out the existence of the malformation. This data will be made available to the Ministry of Health so that measures and technical resources can be implemented to improve pre- and post-natal health.

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Research Ethics Committee Approval: The project was approved by the Independent Ethics and Research Committee of the Faculty of Medicine of the Agostinho Neto University, according to DECISION Nº 15/01-PAR/CE/FMUAN/2023, of August 26, 2023, Being a secondary-based study, the names of the newborns in the sample were omitted, photographs were not taken of the clinical processes,in accordance with the standards of the Declaration of Helsinki.

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Supplementary Materials: None.

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